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1. Submitter Name, Address, and Date of Submission:

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Contact: Same as above.

2. Names of the Device, Common, Proprietary(if Known), and Classification.

Classification Name: Secondary Trocar with Sleeve

Common Name: Reusable Trocar with Sleeve

3. Identification of the legally marketed device to which the submitter claims equivalence.

The Pilling Weck Trocar and Sleeve is substantially equivalent to the Core Dynamics Entree II, Apple Medical Hunt Reich Secondary Trocar, and the Access Surgical Access Single Use Trocar and Sleeve.

4. Description of the Device:

The device consists of Reusable Trocars and Sleeves, with available Single Use Disposable Caps. The Disposable Cap Assembly consists of a universal adapter seal, which is used as a port of entry for the instrument/probe and used to minimize leakage and loss of pneumoperitoneum.

The Disposable Cap Assembly is packed sterile in individual pouches or two to a pouch.

The Reusable Trocar, sizes 3mm.-11mm. , is constructed with a stainless steel shaft and is available in pyramidal style.

The Sleeve, proportionally sized, is made of polymer and accepts the Disposable Cap Assembly to seal the port of entry for the surgical instrument.

A Teletex Company

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5. Intended Use of the Device:

The Reusable Trocar and Sleeve are manual surgical instruments used to support a cut down(lap approach) on secondary puncture placement. The trocar is used in Endoscopic Surgery(Abdominal and Thoracic) for incision and peritoneal access for positioning of the hollow sleeve.

Once the trocar is removed, the port of entry provided by the sleeve, through the cap, is used with manual surgical instruments, endoscopic instruments, laproscopes, and probes. There is an seal on the cap, which closes the port of entry.

The usage of this product is identical to previous devices, which have the same technological characteristics.

6. Summary of Technological Characteristics:

The following technological characteristics are the same or equivalent as predicate devices:

The Reusable Trocar, consisting of a hub with a stainless steel shaft is equivalent to the predicates.

The sleeve used with the Trocar is treaded, which is equivalent to the predicates.

The Cap Assembly is contains the seal, which is used to minimize the leakage from the pneumoperitoneum, which is equivalent to the predicates.

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